

REMARKS

This Replacement Amendment and Response is in response to the Examiner's communication dated 9 April 2004 requesting a

"discussion as to how the cited prior art reads or does not read on the claims as now presented."

The purpose of this communication is to comment on the patentable distinctions in the current claims with respect to the cited art. An amendment to claim 52 is added to indicate the location of the stent in the two-layer coating of the stent.

In an attempt to rapidly promote the prosecution, Applicants withdrew the original claims and substituted a new set of claims believed to be patentable over the prior art. Applicants assert that the new claims are patentable over art cited by the Examiner. Claims 42-61 are before the Examiner. Applicants assert that claim 42 is allowable, since the claim relates to a stent having a two layer coating, each layer comprising a polymer and each containing a biologically active substance. In one embodiment, the first layer acting as a fast release layer and the second layer acting as a slow release layer. The intermediate layer, between the stent and the external coating, also can act as an adhesive layer that maintains coating integrity. This structure having a two-layer coating, each coating based on a polymer and containing a biologically active substance is novel and unobvious in light of the prior art. In large part, the prior art teaches single layer coatings and if a second coating is used, these coatings do not contain biologically active substances. A slow release film is not a polymeric layer as is claimed. Regarding claim 43, having a biodegradable substance in the external layer is novel in that structure. Similarly, claim 44 having an adhesive layer, as the intermediate layer is novel. The subject matter of claim 45 having two biologically active compositions in the intermediate layer is novel. One of ordinary skill in the art would not place biologically active substances in an intermediate layer since their activity would not be immediately available to the implanted stent. Similarly, having an external layer with two biologically active substances is not suggested for this structure. The nature of the polymers in claims 47 and 48 are not known for the purpose of the overall structure of the independent claim. In claims 49 and 50, the use of anti-inflammatory materials in the structure of the independent claims is not known. The polymeric materials in claims 52 and 53 are unknown for the structure of the independent claims. The structure of dependent claim 54 is

uniquely structured to provide a two-phase treatment motif. In this motif, restenosis is prevented by a rapid release of relatively active (or high concentration) of a first treatment material or active biological material in the first ninety days of implantation. Once that layer has been released and removed from the stent, the second internal or adhesive layer remains providing long term treatment for ninety days plus using a treatment material that releases slowly over a period of time, substantially greater than ninety days. This two-phase treatment protocol provides an anti-restenosis activity not present in prior art structures. The treatment material is claims 51, 55, 56, in the multilayer structure of claim 43 is unknown in that configuration. The structures of claims 58 and 59 adding additional biostable or biodegradable layers to the bi-layer structure of claim 43 is further unobvious since the prior art is typically single layer, single treatment material.

The above discussion points out the patentability of each claim now present and available for the Examiner's review.

Conclusion

Applicants view is that the commercial stent structures, to date, typically involved single layer, single polymer, and single biologically active treatment motifs. We believe these commercial structures are reflected in the cited reference, Eury, EP 734 721, the closest cited prior art that does not suggest that two or more layers can be formed on a stent having, in each layer, at least one biologically active substance. In view of the above amendments and remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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Date

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